UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

07/346,165 05/02/89 FERRARA N 479581

GUEST,S

PHILLIPS, MOORE, LEMPIO & FINLEY
177 POST STREET, STE 800
SAN FRANCISCO, CA 94108

186 14

03/01/91

☒ This application has been examined ☒ Responsive to communication filed on 12/6/90 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-40 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 6-11, 26-32, 37 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-5, 12-25, 33-36, 38-40 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

The rejection made under 35 USC 101 in regards to non-statutory subject matter is withdrawn in light of applicant's amendment and arguments filed in paper number 13.

The following rejections are maintained for the reasons stated below and in the last office action: 1) the obviousness double patenting rejection over 328181, 2) the rejection under 35 USC 101 for double patenting over 346046, 3) the rejection made under 35 USC 112, 1st paragraph, and 35 USC 101 in regards to lack of enablement and utility in view of Dr. Gospodarowicz's letter, 4) the rejection made under 35 USC 112, 1st paragraph in regards to lack of enablement, 5) the rejection made under 35 USC 112, 2nd paragraph, 6) the rejection made under 35 USC 102(b)/103 over Burgess et al. and Winkles et al.

The Abstract of the Disclosure is objected to because it is two paragraphs in length. It must only be one paragraph. Correction is required. See M.P.E.P. § 608.01(b).

Claims 1-5, 12-25, 33-36, and 38-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, and

13-16 of copending application serial no. 07/328181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant applicant merely further limits the claims of the earlier application, however the inventions are inherently the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 12-25, 33-36, and 38-40 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-5, 12-25, 33-36, and 38-40 of copending application Serial No. 346046. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-5, 12-25, 33-36, and 38-40 are rejected under 35 U.S.C. §101 as lacking utility, or under 35 U.S.C. 112, first paragraph as failing to enable any person skilled in the art to which it pertains to practice the claimed methods and therefore obtain the claimed growth factor. Applicant has stated in response to this rejection that scientific and legal investigations have been conducted and determined that Dr. Gospodarowicz's allegations were unwarranted. Written copies of documents stating the conclusions of UCSF and Genetech, Inc., and

possibly a statement by Dr. Gospodarowicz should be made of record in this case to overcome this rejection.

Claims 19-20, and 40 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the growth factor purified from natural sources. Applicant argues that in view of the state of the art, one of ordinary skill would be able to obtain the factor without undue experimentation. This argument is not deemed persuasive since applicant does not give any reasoning behind this argument. Furthermore, without the gene sequence available, producing a protein by recombinant involves undue experimentation. This involves, determining homologous sequences, designing a probe, screening a cDNA library, isolating the clone, cloning into an expression vehicle, and properly expressing the desired protein. This constitutes an incredible amount of work, and multitudes of unpredictable factors. Applicant must provide reasons why it is believed that the above processes would be considered routine.

Claims 1, 2, 15, 21-25, 36, and 40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is identical to claim 1, claims 22-25 are collectively identical to claim 2, and claim 36 is identical to claim 15, and are therefore

confusing. Claim 40 is confusing as to the term "certain" in referring to the amino acids in parenthesis. Does this mean the amino acids not in parenthesis are uncertain? This is unclear. This rejection will not be withdrawn until the identical claims are canceled and the rejection of claim 40 is adequately addressed.

Claims 1-5, 12-25, 33-36, 38-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Burgess et al.

Claims 1-5, 14-16, 18-25, 34-36, 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Winkles et al.

Applicant's response to these rejections is considered non-responsive. Applicant merely states that Burgess et al. and Winkles et al. describe an acidic form of FGF, and that this protein is significantly different from the claimed protein. No explanation is given to explain the differences. It is explicitly stated in the previous office action that in order to overcome a rejection under 35 USC 102/103, comparative data or explanations showing the differences between the claimed protein and that of the prior art must be submitted. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between

the claimed product and the product of the prior art (i.e. that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1923 (PTO Bd. Pat. App. & Int.).

The following is a new ground of rejection:

Claims 1-5, 12-25, 33-36, and 38-40 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-5, 12-15, 33-36, and 38-40 of copending applications Serial Nos. 07/360229 and 07/360235. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION

IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shelly Guest whose telephone number is (703) 308-4310. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. Moskowitz

MARGARET MOSKOWITZ
SUPERVISORY
PATENT EXAMINER
ART UNIT 186

sjg
February 28, 1991